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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/767,041	01/22/2001	Hilda E. Smith	4726US	3344

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EXAMINER
DUFFY, PATRICIA ANN

ART UNIT	PAPER NUMBER
1645	10

DATE MAILED: 03/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/767,041	Smith et al
Examiner	**Art Unit**
Patricia A. Duffy	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *one* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-33* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
   - I. Claims 1-9 and 30, drawn to nucleic acids, classified in class 536, subclass 23.7.
   - II. Claims 10 and 11, drawn to polypeptides, classified in class 435, subclass 183.
   - III. Claim 12, drawn to a process for producing a capsular antigen using the protein, classified in class 435, subclass 72.
   - IV. Claim 13 and 14, drawn to a capsular antigen, classified in class 514, subclass 54.
   - V. Claims 15 -25 and 31-33, drawn to *Streptococcus suis* mutants, classified in class 435, subclass 253.4.
   - VI. Claim 26, drawn to method of vaccination using *Streptococcus suis* mutants, classified in class 424, subclass 244.1.
   - VII. Claims 27-29, drawn to method for controlling Streptococcal disease by detecting microorganisms or antibodies, classified in class 435, subclass 7.34.
2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions I, II, IV and V are related as products. The products are distinct each from the other because neither product is required to produce any of the others, they have different chemical structures and can be produced by different methods. For example, the nucleic acids of Invention I are not required to produce the polypeptides of Invention II because the polypeptides could be isolated from nature or produced by synthetic methods. The nucleic acids of Invention I are not required to produce the capsular antigen. The nucleic acids of Invention I are not required to produce the microorganisms of Invention V because the microorganisms could be produced for chemical mutation or screening for capsular variants from nature. The polypeptides of Invention II are separate and distinct from the capsular antigen of Invention III because the capsular antigen could be isolated from nature or produced synthetically. The polypeptides of Invention II are not required for the production of the microorganism. Furthermore, the Inventions are chemically distinct, nucleic acid, amino acid, carbohydrate and intact microorganism respectively, necessitating different non-coextensive art searches.

4. Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05(h)). In the instant case the enzymatic polypeptides can be used in an *in vitro* method of screening for enzymatic inhibitors for potential use as antibiotics to treat Streptococcal disease.

5. Inventions V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the *Streptococcus suis* mutants can be used to produce heterologous polypeptides or in a method of differential diagnosis or in a method of determining inhibition by antibiotics.

6. Inventions III and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the capsular antigen can be isolated from nature or produced synthetically.

7. Inventions I and II, are drawn to multiple individual chemically and functionally distinct polynucleotides and polypeptides. The claims are drawn to numerous patentably distinct nucleic acids or polypeptides, each of which constitutes a patentably distinct product. Although the classifications for these various nucleic acids are overlapping, for instance 536/23.7, each represents a patentably distinct product with distinct physical and functional characteristics. Further the search for more than one product would be burdensome, because each is claimed not by nucleic acid sequence, but by the sequence of the protein encoded thereby, and requires a search of the corresponding region of SEQ ID NO: X as well as a 'reverse translation' search of the corresponding region of SEQ ID NO: Y, such that each individual sequence requires two sequence searches which are not required for any of the other sequences, or alternatively by virtue of comprising only a small portion of a disclosed nucleic acid, which requires a separate "word search" of the nucleic acid databases, or by claiming nucleic acids which 'hybridize' to a disclosed nucleic acid, which requires a broader search of the nucleic acid databases. Due to the use of 'comprising' language, it cannot even be said that the search for nucleic acids encoding amino acids of a particular sequence of amino acids 1-160 of SEQ ID NO: Z would reveal art pertaining to, for instance a nucleic acid *comprising* a region encoding amino acids 171-

182 of SEQ ID NO: Z, as the latter could be found embedded in a completely different protein. The same arguments apply to the polypeptides. Accordingly, restriction is proper. Should applicant elect either Group I or Group II applicant should elect a ***single*** polynucleotide or a ***single*** polypeptide for prosecution on the merits will be restricted. This requirement is not to be construed as a species election.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification, restriction for examination purposes as indicated is proper.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Tuesday-Saturday from 10:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

Patricia A. Duffy, Ph.D.
March 24, 2002

Patricia A. Duffy
Patricia A. Duffy, Ph.D.
Primary Examiner
Group 1600